

6727/OK095

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)****10/009847**

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/IL00/00336

07 June 2000

08 June 1999

TITLE OF INVENTION

**NEONATAL AIRWAY ADAPTOR**

APPLICANT(S) FOR DO/EO/US

**Lewis COLMAN; Gershon LEVITSKY**

Applicant herewith submits to the United States Designated/Elected office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S. C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S. C. 371 (b) and PCT Articles 22 and 39 (1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S. C. 371 (c) (2) )
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. ☐ A translation of the International Application into English (35 U.S. C. 371 (c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c) (3)).
9. ☒ An (UNSIGNED) oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

**Items 11. to 16. below concern other document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98 (with references).
12. ☐ An assignment document for recording. A **separate** cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment. **+ mark-up version**  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney an/or address letter.
16. ☐ Other items or information:

**EXPRESS MAIL CERTIFICATE**Date **12/7/01** Label No. **61004807035US**

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service &amp; that it was addressed for delivery to the Assistant Commissioner for Trademarks, 2900 Crystal Drive, Arlington, VA 22202-8513 by "Express Mail Post Office to Addressee" service.

Name (Print) **DB Peck**Signature **DB Peck**

U.S. APPLICATION NO. (if known see 37 C.F.R. 1.50)

10/009847

INTERNATIONAL APPLICATION NO.: PCT/IL00/00336

Attorney's Docket Number  
6727/OK095

17. [x] The following fees are submitted:

**Basic National Fee (37 CFR 1.492 (a)(1)-(5)):**

Search Report has been prepared by the EPO [X] or JPO []

\$890.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)

\$710.00

No international preliminary examination fee paid to USPTO (37 CFR 1.482)  
but international search fee paid to USPTO (37 CFR 1.445 (a) (2))...

\$740.00

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....

\$1,040.00

International preliminary examination fee paid to USPTO (37 CFR 1.482)  
and all claims satisfied provisions of PCT Article 33(2)-(4)....

\$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =

\$710.00

Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30  
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

Claims	Number Filed	Number Extra	Rate		
Total Claims	22-20	2	2 X \$18.00	\$36.00	
Independent Claims	2-3	0	X \$84.00	\$ .00	
Multiple dependent claims(s) (if applicable)			+ 280	\$	
TOTAL OF ABOVE CALCULATIONS =				\$746.00	
Reduction by 1/2 for filing by small entity, if applicable.				\$ .00	
SUBTOTAL =				\$746.00	
Processing fee of \$130.00 for furnishing the English translation later the [ ] 20 [ ] 39 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	\$
TOTAL NATIONAL FEE =				\$746.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). the assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$0.00
TOTAL FEES ENCLOSED =				\$746.00	
				Amount to be: refunded	\$
				charged	\$

a. [X] A check in the amount of \$746.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. 04-0100 in the amount of \$ to cover the above fees.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit  
Account No. 04-0100. A duplicate copy of this sheet is enclosed.**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed  
and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

S. Peter Ludwig  
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805 Third Avenue  
New York, New York 10022-7513

SIGNATURE

NAME S. Peter Ludwig

REGISTRATION NO. 25,351

EXPRESS MAIL CERTIFICATE

Date \_\_\_\_\_ Label No. \_\_\_\_\_  
I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Name (Print) \_\_\_\_\_

Signature \_\_\_\_\_

Customer No.: \_\_\_\_\_



07278

PATENT TRADEMARK OFFICE

Docket No: 6727/OK095

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lewis COLMAN et al.

Serial No.: Not Yet Assigned

Art Unit: N/A

Filed: Concurrently herewith

Examiner: N/A

For: **NEONATAL AIRWAY ADAPTOR**

PRELIMINARY AMENDMENT

Hon. Commissioner of  
Patents and Trademarks  
Washington, DC 20231

December 7, 2001

Sir:

Prior to examination, please amend the above-identified application as follows:

**In the specification:**

On page 1, after the title and before BACKGROUND OF THE INVENTION, insert:

EXPRESS MAIL CERTIFICATE

12/7/01 6400 4807 035 US  
Date \_\_\_\_\_ Label No. \_\_\_\_\_  
I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents and Trademarks, 2900 Crystal Drive, Arlington, VA 22202-3514 by "Express Mail Post Office to Addressee" service.

Name (Print) \_\_\_\_\_

Signature \_\_\_\_\_

-- This application is a National Phase (371) of PCT application no. PCT/IL00/00336, filed June 7, 2000, which was published in English on December 14, 2000.--

**In the claims:**

Amend claims 14, 15, 16, 20, 21 and 22 as follows.

14. (Amended) An airway adaptor according to claim 12, and wherein an internal diameter of said passage increases towards an end of said passage near said sampling port.

15. (Amended) An airway adapter according to claim 12, and wherein said inner bore of said passage has an internal diameter essentially equal to the internal diameter of said inner bore of said endotracheal tube adapter, thereby providing an approximately smooth-walled transition from said inner bore of said endotracheal tube adapter to said inner bore of said passage.

16. (Amended) An airway adaptor according to claim 12, and wherein said end of said sleeve distant from said sampling port abuts against said end of said inner bore of said endotracheal tube passage, thereby resulting in virtual elimination of void volume between said inner bore of said endotracheal tube adapter and said internal bore of said sleeve.

20. (Amended) An airway adapter according to claim 12, and wherein said sampling port has openings located radially distant from the walls of said passage.

21. (Amended) An airway adapter according to claim 1, and wherein an end of said sleeve distant from said sampling port is constructed of a pliant material.

22. (Amended) An airway adapter according to claim 1, and operative to nullify the effects of differing internal diameters and internal lengths which are used in endotracheal tube adaptors.

#### **REMARKS**

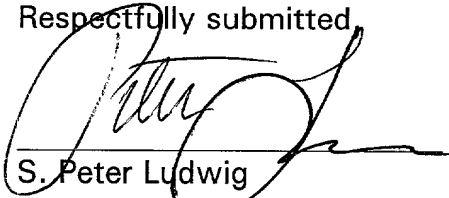
The specification has been amended to make reference to the prior application.

Claims 14, 15, 16, 20, 21 and 22 have been amended to eliminate any multiple claim dependency. This is being done to reduce filing fees and not for any reason related to patentability of such claims.

A marked-up version of the amendments pursuant to 37 CFR 1.121 is enclosed.

Entry of this amendment is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'S. Peter Ludwig', is written over a horizontal line.

S. Peter Ludwig

Reg. No. 25,351

Attorney for Applicant(s)

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10/5

## NEONATAL AIRWAY ADAPTOR

### FIELD OF THE INVENTION

The present invention relates in general to the field of airway adapters for the connection of an endotracheal tube to ventilation apparatus, particularly for use with neonatal patients.

### BACKGROUND OF THE INVENTION

Airway adapters are generally used with patients being given respiratory assistance, such as patients under anesthesia, or patients on life support systems, to connect between the endotracheal tube (ET tube) and the ventilating tube of the breathing apparatus. These tubes convey breathing gases to the patient and exhaled breath away from the patient. The airway adapter is in the form of a short connector of tubular shape, and is required to make a connection between the generally very different cross sections of these two tubes. The airway adapter connected directly to the endotracheal tube is known as the ET adapter. Airway adapters also have the function of providing a demountable joint in the ventilation path, for the insertion of other tubes into the patient's lungs, and for the dispensing of medication into the pulmonary areas. This is necessary since it may be difficult to remove the ET itself from its connector port, without disturbing the patient or his treatment.

A non-invasive indication of the patient's respiratory condition can be obtained by the analysis of the exhaled breath gases. The measurement of the dynamic carbon dioxide content of the exhaled breath is known as capnography. Airway adapters with sampling ports are used to collect gas samples from the exhaled breath of patients for analysis. ET adapters are also available with a small-bore port extending into the wall of the gas flow path, to collect samples of the gas flowing in the airway, for gas analysis. Since, however, capnography

measurements are generally not performed on a continuous basis, and the use of a sampling ET adapter would thus necessitate the sealing of the sampling port for most of the time, and the potential danger of bacterial growth in any debris lodged in the blind sampling tube, such sampling ET adapters are not generally used, a priori, for intubated neonatals. Furthermore, the termination of the sampling ports in the wall of the ET adapter airway is likely to cause the ingestion of secretions and liquids into the gas analyzer through the sampling line, especially during pulmonary suction procedures, when liquids could be sucked straight from the lungs into the sampling port opening. To avoid this problem, ET adapters are available with a sampling port extending into the center of the bore. This, however, interferes with the insertion of other tubes and apparatus down the ET tube.

For all of the above reasons, a generally used procedure with neonatals is not to use a sampling ET adapter on commencement of intubation, but to add an airway adapter with sampling port later, if and when required.

The accuracy of the capnographic measurement depends on the maintenance of a smooth laminar flow of the patient's breath through the airway adapter, so as to maintain the waveform of the exhaled breath. The waveform, which is the time varying level of carbon dioxide in the patient's breath, contains detail which can change with a response time of 10 to 100 msec. The exact form of the waveform, including these fast variations, provides information about the patient's respiratory state. Internal mixing of the gases or alterations in the waveform reduce the accuracy of the capnographic measurement by slowing down the response time, and hence reduce the amount or accuracy of diagnostic information extractable from the capnograph.

Airway components are typically made as plastic injection moldings, to enable production costs to be kept low. In order to ensure gas tight joins, components to be connected are generally produced with slight tapers, such that one component fits snugly into the other. Because of the comparatively wide manufacturing tolerances of such plastic parts, there is a wide spread in the



closed dimensions of a joined pair of matching parts. Thus for instance, a loose-fitting ET adapter/ventilation tube connector pair will seal when one part is pushed much further into the other, than a tight-fitting pair. As a consequence of this, the amount of void volume (also known as dead space) produced in such a connection is very variable, and for a tight fitting pair, could be very considerable. The airway adapter should have minimal added void volume, both to reduce the effects of gas mixing, which would adversely affect the integrity of the waveform, and to reduce the anatomical dead space, which results in rebreathing.

Furthermore, the exhaled breath of patients always contains condensable water vapor, and can also contain a significant level of liquid or solid secretions such as mucous secretions and saliva. Such liquids can block or partially block the sampling line, causing a reduction in the pressure of the gases passing through the airway adapter into the gas analyzer. This pressure drop can cause alterations in the waveform, mixing of the gas, and alterations in the gas concentration, all of which reduce the accuracy of the gas analysis. The need for accurate analysis of the gas therefore dictates efficient separation of the gas from accompanying liquids or solids, while maintaining smooth laminar flow, and without the production of a substantial pressure drop or alteration in the gas waveform.

A number of novel designs for such airway adapters have been presented in U.S. Patent No. 5,857, 461, entitled "Multiple Channel Sample Port" to the present Applicants, and hereby incorporated in its entirety by reference. Furthermore, in the Background section of that patent are mentioned a number of other patents which describe airway adapters of other designs. However, none of the airway adapters described therein are satisfactory for use with neonatals. A major problem with neonatal patients is the very small flow involved. Thus for instance, a neonatal may typically exhale breaths of only 4 cc., while the volume of a standard adult airway adapter is 6 to 8 cc. This means that even a very small void volume can cause significant mixing of the neonatal's exhaled breaths, and

inaccurate capnographic results. Furthermore, the fast breathing rate of neonatals makes a fast response time even more critical than for other patients. In addition, it is impractical to disconnect the ET tube of an intubated neonatal in order to change the ET adapter to fit the sampling device to be used. Finally, closed circuit systems which include suction are widely used, and it is impractical to break such circuits in order to insert and remove capnographic adapters as needed.

There therefore exists a serious need for a sampling airway adapter, especially for use with neonatal patients, which overcomes the drawbacks and disadvantages which hitherto available adapters show when used with such patients.

The disclosures of all publications mentioned in this section and in the other sections of the specification, are hereby incorporated by reference, each in its entirety.

## SUMMARY OF THE INVENTION

The present invention seeks to provide a new airway adapter of novel construction which enables its use with neonatal patients without detracting significantly from the accuracy of capnographic measurements being performed on the patient, and without interfering unduly with the ventilation of the patient.

There is thus provided in accordance with a preferred embodiment of the present invention, a neonatal airway adapter which virtually eliminates void volumes (dead space) within the bore of the airways, such that mixing of the exhaled gases with void gases is reduced to minimal levels, and the waveform of the breath is maintained without unnecessary distortion. Furthermore, the virtual elimination of void volumes is clinically beneficial to the patient, since void volumes prevent the dispersion of the exhaled carbon dioxide, and cause a higher level of rebreathing. For this reason too, the neonatal airway adapter according to the present invention adds a minimal length to the airway circuit, in a situation

where any excess length makes the dispersion of exhaled carbon dioxide more difficult.

Furthermore, according to a further preferred embodiment of the present invention, the neonatal airway adapter connects to endotracheal tube adapters in such a way as to nullify the effect of the differing internal diameters and internal lengths which are used in ET adapters currently available.

In addition, according to a further preferred embodiment of the present invention, the cross-section of the internal bore of the airway through which the breath flows from the ET adapter to the connector of the ventilator is maintained almost constant, especially in the region of the gas sampling point, to ensure that reasonable conditions of laminar flow are maintained.

The additional response time added to the response time of the rest of the airway system by a neonatal airway adapter according to preferred embodiments of the present invention, is minimal, such that the accuracy of capnographic measurements being performed on the neonatal patient are virtually unaffected.

In order to minimize the ingress of secreted liquids or breath-borne moisture into the gas analyzer sampling line, according to a preferred embodiment of the present invention, the gas sampling point is located in the center of the airway bore, away from the walls, in such a position as to reduce the liquid entrance level by a significant factor compared with prior art airway adapters. This factor too assists in avoiding clogging of the sample line, which would affect the faithfulness of waveform transmission, and by reducing the initial moisture level of the analyzed gas, also improves analysis accuracy.

Another advantage of an airway adapter according to a preferred embodiment of the present invention, is that since it has a minimally short length, it does not interfere unduly with the ventilation of the patient, and is not unduly cumbersome. Thus, even when capnographic measurements are not required, it can be left in circuit without affecting the well-being or treatment of the patient, and likewise, when used with closed circuit suction systems. This is in contrast with prior art adapters, which often need to be removed from circuit when not in

use, this being a complex action with an intubated neonatal. Furthermore, the risk of infection is reduced if the breathing circuit is not disturbed.

In accordance with yet another preferred embodiment of the present invention, there is provided an airway adapter consisting of a first end section for connecting to an endotracheal tube adapter having an inner bore, the first end section having a passage formed therein, a second end section for connecting to a ventilating tube connector, the second end section being in fluid communication with the first end section, a sampling port intermediate the end sections in fluid communication with the first end section, and a tubular insert with an internal bore, which slides axially in the passage.

There is further provided in accordance with yet another preferred embodiment of the present invention an airway adapter as described above and wherein the internal diameter of the internal bore of the insert gradually increases towards an end of the insert near the sampling port, such that the internal diameter of the internal bore becomes essentially equal to the internal diameter of the passage.

In accordance with still another preferred embodiment of the present invention, there is provided an airway adapter as described above and wherein the insert has a projection adapted to abut against a portion of the first end section, which provides an axial motion limit into the passage, or wherein the projection consists of a lip on the external wall of the insert.

In accordance with a further preferred embodiment of the present invention, there is also provided an airway adapter as described above and wherein an outer wall of the insert has a surface profile such that the friction between the insert and the passage prevents the insert from sliding freely within the passage.

There is further provided in accordance with still another preferred embodiment of the present invention an airway adapter as described above and wherein the internal bore of the insert at an end of the insert distant from the sampling port, has an internal diameter essentially equal to the internal diameter

of the inner bore of the endotracheal tube adapter, thereby providing a virtually smooth-walled passage from the inner bore of the endotracheal tube adapter to the internal bore of the insert.

There is provided in accordance with yet a further preferred embodiment of the present invention an airway adapter as described above and wherein the end of the insert distant from the sampling port abuts against the end of the inner bore of the endotracheal tube passage, thereby resulting in virtual elimination of void volume between the inner bore of the endotracheal tube adapter and the internal bore of the insert.

There is even further provided in accordance with a preferred embodiment of the present invention an airway adapter as described above and wherein the virtually smooth-walled passage is operative to allow a breath waveform to pass essentially without affecting its waveform.

Furthermore, in accordance with yet another preferred embodiment of the present invention, there is provided an airway adapter as described above and wherein the virtual elimination of void volume is operative to allow a breath waveform to pass essentially without affecting its waveform.

There is also provided in accordance with a further preferred embodiment of the present invention an airway adapter as described above and wherein the sampling port has openings located radially distant from the side walls of the passage.

In accordance with yet another preferred embodiment of the present invention, there is provided an airway adapter consisting of a first end section for connecting to an endotracheal tube adapter having an inner bore, the first end section having a passage formed therein, the passage having an outer wall, a second end section for connecting to a ventilating tube connector, the second end section being in fluid communication with the first end section, a sampling port intermediate the end sections in fluid communication with the first end section, and a tubular sleeve with an internal bore, which slides axially on the outer wall of the passage.

There is further provided in accordance with yet another preferred embodiment of the present invention an airway adapter as described above and wherein an internal diameter of the inner passage increases towards an end of the passage near the sampling port.

There is further provided in accordance with yet another preferred embodiment of the present invention an airway adapter as described above and also consisting of a spring operative to push the sleeve axially in a direction away from the sampling port.

In accordance with still another preferred embodiment of the present invention, there is provided an airway adapter as described above and wherein the internal bore of the inner passage has an internal diameter essentially equal to the internal diameter of the inner bore of the endotracheal tube adapter, thereby providing a reasonably smooth-walled passage from the inner bore of the endotracheal tube adapter to the internal bore of the inner passage.

There is further provided in accordance with still another preferred embodiment of the present invention an airway adapter as described above and wherein the end of the sleeve distant from the sampling port abuts against the end of the inner bore of the endotracheal tube passage, thereby resulting in virtual elimination of void volume between the inner bore of the endotracheal tube adapter and the internal bore of the sleeve.

In accordance with a further preferred embodiment of the present invention, there is also provided an airway adapter as described above and wherein the virtually smooth-walled passage is operative to allow a breath waveform to pass essentially without affecting its waveform or wherein the virtual elimination of void volume is operative to allow a breath waveform to pass essentially without affecting its waveform.

There is provided in accordance with yet a further preferred embodiment of the present invention an airway adapter as described above and wherein the virtual elimination of void volume between the inner bore of the endotracheal tube adapter and the internal bore of the insert is effective independently of the

relative position in which the endotracheal tube adapter and the airway adapter are mated.

Furthermore, in accordance with yet another preferred embodiment of the present invention, there is provided an airway adapter as described above and wherein the virtual elimination of void volume between the inner bore of the endotracheal tube adapter and the internal bore of the sleeve is effective independently of the relative position in which the endotracheal tube adapter and the airway adapter are mated.

There is also provided in accordance with a further preferred embodiment of the present invention an airway adapter as described above and wherein an end of the insert distant from the sampling port is constructed of a pliant material.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Fig. 1 is a cross-sectional view of a prior art airway connection made between an endotracheal tube (ET) adapter and a ventilation tube connector;

Fig. 2 is a cross-sectional view of a neonatal airway adapter, constructed and operative in accordance with a preferred embodiment of the present invention;

Fig. 3 is a cross-sectional view of a neonatal airway adapter, constructed and operative in accordance with another preferred embodiment of the present invention, having an alternative gas sampling outlet to that shown in Fig. 2, the adapter being shown connecting an ET adapter to a ventilation tube connector;

Fig. 4 is a cross-sectional view of a neonatal airway adapter like that shown in Fig. 3 but in a more fully closed position when connected to an ET adapter; and

Fig. 5 is a cross-sectional view of a neonatal airway adapter, constructed and operative in accordance with yet another preferred embodiment of the present invention, which uses an alternative method of ensuring a gas-tight seal with the ET adapter to which it is attached.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a cross-sectional view of a prior art airway connection made between an endotracheal tube (ET) adapter 10 and a ventilation tube connector 24, typically attached at its remote end to breathing apparatus. One end of the ET adapter 10 is formed into a narrow tubular section 12, having a wall and a central bore 14, over which the end of ET tube itself is fitted. Neonatal ET tubes are available in sizes ranging from 2.5 to 4 mm. The exhaled and breathing support gases are passed from and to the patient through this bore 14. The ET tube is attached over this tubular section which generally has an inner diameter (ID) of 3.5mm, this being suitable for most neonatal ET tubes. This ET adapter can also be provided with a gas monitoring port, terminating at a hole 39 in the ET adapter wall.

At the other end of the ET adapter, there is a wide bore tubular opening having a wall 16 and a central bore 22 of similar size to that of the ventilation tube. The ventilation tube has to be of wide bore, since ventilation tubes are typically 2 meters long, and a narrow bore, like that of the ET tube, would severely limit the breathing gas conduction. The outside diameter (OD) 18 of the tubular opening is of a generally standard size, whereas the inside diameter (ID) 20 and the length L are not of universally standardized size. The ventilation tube connector 24 is attached to the ET adapter by sliding the outer wall 26 of the ventilation tube connector over the wall 16 of the wide bore tubular opening of the ET adapter. The outer wall 16 of the wide bore tubular opening of the ET adapter has a very slight conical taper, narrowing towards the ventilation tube



end, and the inner surface 28 of the outer wall 26 of the ventilation tube connector has a matching conical taper, widening towards the ET adapter end, such that when assembled, the two parts form a good gas-tight connection.

However, when the ET adapter 10 is connected to the ventilator connector 24, the large hollow space of the central bore 22 of the ET adapter may interfere with any waveform measurement performed along the airway, because of the void volume (also known as dead space) formed therein. Furthermore, in the region 30 where the central channel widens from the ET diameter 14 to the ventilation tube connector diameter, which is of similar size to the central bore 22, the abrupt change in diameter causes the formation of eddies in the gas, which destroy the smooth laminar flow, and damage the integrity of the breath waveform. Since this takes place very close to the breath sampling point 39, the sampled waveform is distorted.

In some prior art adapters, an attempt is made to fill this void volume and to eliminate the abrupt diameter change, by means of a second, inner tubular wall 32 protruding from the connector body 24, which fills part of the hollow space inside the ET adapter. However, as previously mentioned, such airway components are typically made as plastic injection moldings, to enable production costs to be kept low. In order to ensure gas tight joins, the components are generally produced with slight tapers, such that one component fits snugly into the other. Because of the inevitable manufacturing tolerances of such plastic parts, and because of the very slight angle of the conical tapers, there may be a wide spread in the closed dimensions of a pair of matching parts when fully mated.

Consequently, the inner tubular wall 32 is often not fully successful in eliminating the void volume, since there will be a space between the outer end 36 of the connector and the inner wall 38 of the ET adapter where the ID increases stepwise, the size of the space depending on how far the ET adapter slides into the ventilating tube connector before making a tight join. The abrupt change in internal diameter of the central bore, and the void volume 30, thus remain.

Furthermore, different types of ET adapter have different ID's 20, such that the internal excess space produced circumferentially when the ET adapter and the ventilation tube connector are mated is not always eliminated.

When there is need to monitor the breath of the patient, because of the drawbacks mentioned above of the ET adapter with built-in sampling port, a sampling adapter is often inserted between the ET adapter and the ventilation tube connector. This involves opening the airway connection, with its concomitant disturbance to the patient's respiratory care, and an increased danger of infection.

Reference is now made to Fig. 2, which is a cross-sectional view of a neonatal airway adapter 50, constructed and operative in accordance with a preferred embodiment of the present invention. The neonatal airway adapter 50 is inserted between an ET adapter and a ventilation tube connector of a respiratory support and monitoring circuit. The airway adapter 50 is preferably constructed of an injection molded plastic material in the form of a series of tubular sections connected axially, such that the respiratory gases can pass down their length. A central passage 52 preferably has an internal bore of approximately 3.5mm, this being a suitable internal diameter (ID) for commonly used neonatal ET tubes.

A tubular insert 54 is located inside the central passage 52. The insert 54 can slide in an axial direction 56 with a close fit on the inside wall 55 of the central passage 52 of the airway adapter. An element of friction can be added between the insert 54 and the inside wall 55 of the central passage 52, by means of fine teeth or grooves in the sliding surface of either part, such that the insert essentially remains in the position to which it is slid. The inside bore diameter 76 of the sliding insert 54 is preferably similar or equal to the inside diameter of the narrow tubular bore of ET adapters. At the inner end of the tubular insert 54, the internal passageway opens out into a funnel shaped section 70, such that along the length of the funnel shaped section, the internal diameter 76 of the insert increases from the value it has along the major length of the insert, until at its

extremity, it becomes equal to the internal diameter of the central passage 52 of the neonatal airway adapter.

The motion of the tubular insert 54 into the central passage 52 is preferentially limited by an outer end section 74 of slightly increased outer diameter. When the lip of an inner end wall 72 of this increased diameter section abuts on an outer extremity wall 78 of the neonatal airway adapter, the inward motion of the insert is arrested.

The inner surface 68 of the outer wall of the ET end of the neonatal airway adapter has a conical taper, appropriately matched to that provided on the outer wall of ET adapters, designated by dimension 18 in Fig. 1, such that mating of the two forms a gas-tight connection.

The other end 80 of the adapter 50 has a wide bore tubular opening 58, preferentially of similar dimensions to that of the ET adapter shown in Fig. 1, such that a standard ventilator tube connector or a standard flow adapter can be mated with it.

A sampling port arrangement 66 is built into the center section of the neonatal airway adapter to allow attachment of a gas sampling line to convey a sample of the patient's breath to a gas analyzer. The internal bore 60 of the sampling port, according to this preferred embodiment of the present invention, opens into the airway central passage 52 in the form of two small holes 62, 64, supported by the sampling port body structure in the central area of the central passage, away from the walls of the central passage. Their location away from the walls is instrumental in avoiding the ingress into the gas sampling line of secretions and liquids accumulated on the walls of the adapter. The two small holes 62, 64, are located offset from the center line of the central passage, and on either side of the center line, and at different axial positions along the length of the central passage, such that one does not mask the other from the flow of gas along the central passage. Furthermore, two holes are used so that if one hole is blocked by a drop of liquid, held on the end of the hole but not sucked in because of its surface tension, the other hole is available for sampling. Because of the

arrangement of the sampling holes, this adapter is known as the Y-Version. The tubular insert 54 is prevented from impacting the sampling port hole structure by means of the above-mentioned lip 72 abutting onto the extremity end wall 78 of the neonatal airway adapter. This prevents damage to the insert during handling before the neonatal airway adapter is assembled in circuit.

Reference is now made to Fig. 3, which is a cross-sectional view of a neonatal airway adapter, constructed and operative in accordance with another preferred embodiment of the present invention. In order to show how the adapter interfaces with its associated components in the breathing circuit, it is shown connected between an endotracheal tube adapter 90 and a ventilation tube connector 102. The neonatal airway adapter is packed in such a way that when it is removed from its packaging, the tubular insert 110 is fully extended. It maintains this position during transit and storage by the friction existent between the insert 110 and an inside wall 111 of the central passage 116. As the ET adapter 90 is pushed onto the neonatal airway adapter, an inner wall 114 of the ET adapter where the ID increases stepwise, pushes the insert 110 axially inwards. The ET adapter eventually mates with the neonatal airway adapter, and makes a gas-tight fit by virtue of the conical taper match between the outer surface 94 of the ET adapter wall 92 and the inner bore 95 of the outer wall of the ET-end of the neonatal airway adapter.

It is observed in Fig. 3 that as the insert 110 slides down the central passage 116 of the neonatal airway adapter, a void volume 112 originally in contact with the central passage 116 is now isolated therefrom. When the ET adapter and the neonatal airway adapter finally mate, friction maintains the insert 110 in the position it has reached, and the patient's breath flows directly from the ET adapter bore 100 into the central passage 116 without contact with this void volume 112. Furthermore, since the internal diameter of the insert 110 is the same as the 3.5 mm. ID bore of the ET adapter passage, the flowing breath does not meet any abrupt bore changes, resulting in the maintenance of smooth laminar flow, with consequential minimal interference to the breath waveform.

The neonatal airway adapter shown has a slightly different sampling port arrangement 106 than that of the embodiment shown in Fig. 2. A pair of sampling holes 108 and 109 are located at opposite ends of a short axial tube centrally located within the central passage. This arrangement has an advantage in that it has lower production costs than that shown in Fig. 2, and has similar advantages in reducing the possibility of the intake of fluids, and in providing a good response time. Because of the arrangement of the sampling holes, this adapter is known as the T-version.

Reference is now made to Fig. 4, which is a cross-sectional view of a neonatal airway adapter of the type shown in Fig. 3, mated with an endotracheal tube adapter and a ventilation tube connector. However, unlike that shown in Fig. 3, the mating position attained by this particular ET adapter and its neonatal airway adapter is such that the closed length of the pair is much shorter. In spite of the large difference in closed length, it is observed that the only difference seen by the gas flow in the central passage is that the flow length is shorter. The insert 110 has simply moved further down the central passage 116, without the introduction of any significant additional void volumes or any bore dimensional changes. This illustrates a major advantage of a neonatal airway adapter according to these preferred embodiments of the present invention, in that it nullifies the effect of the different production-caused, closed lengths of mated component pairs on either side of it in the airway, virtually without any effect on the flow path itself.

The insert 110 has a funnel-shaped section 124 at its inner end. The function of this funnel shaped section 124 is to compensate for the narrowed cross sectional area of the central passage 116 resulting from the presence of the sampling port structure. In the maximum closed position, the sampling hole 109 facing the direction of the patient is located approximately halfway down the funnel of the insert. In this manner, exactly at the sampling point, where maintenance of the waveform integrity is of high importance, the laminar flow of the breath remains reasonably intact, in spite of the perturbations that the

sampling hole structure would otherwise have introduced. After the sampling holes, the form of the breath waveform is no longer of importance, and the airway passage widens out into the ventilation tube 104, which has a larger cross section to provide good ventilation conductance.

As an additional consideration, the widened funnel section of the insert is operative to gradually increase the distance of the walls of the central passage of the neonatal airway adapter from the sampling holes. Since secreted liquids and condensed moisture tend to flow along the walls of the central passage, this construction also assists in reducing the undesired ingress of such liquids into the sampling holes.

The length of the funnel-shaped section of the insert is determined by a compromise, determinable by those skilled in the art, between the need to provide a gradual increase in diameter of the bore towards the sampling port, and the need to avoid any unnecessary added volume to the airway passage. Important physical features of the internal bore of the insert are that at the end where it abuts the ET tube, it should preferably have the same ID as that of the ET tube adapter, and at the sampling port end, its ID should be enlarged to provide the above-mentioned compensation.

Reference is now made to Fig. 5 which is a cross-sectional view of a neonatal airway adapter, constructed and operative in accordance with yet another preferred embodiment of the present invention. The overall construction and method of use of this embodiment are similar to those shown in Figs. 3 and 4. This neonatal airway adapter differs, however, in two aspects:

firstly, it uses a sleeve instead of an insert to ensure an essentially leak-free seal with the ET adapter to which it is attached, and

secondly, it uses a spring to ensure positive contact between that sleeve and the ET adapter.

The sleeve 140 in this preferred embodiment slides on the outside of the wall 142 of the central passage of the neonatal airway adapter. The funnel shaped enlargement 144 in the airway bore required opposite the sampling holes is

incorporated into the wall 146 of the central passage, and is thus fixed in this position. The sleeve seals against the inner wall 148 of the ET adapter where the ID increases stepwise, preferably by means of a soft elastomer seal 150 with a rounded end attached to the outer end of the sleeve. The seal is maintained in positive contact with the inner wall 148 of the ET adapter, by means of a spring 152 located around the outer wall of the central passage.

The use of a spring has a number of other advantages also. Firstly, it maintains the sleeve in the fully extended position during shipping and handling, until the airway adapter is ready to be attached to its mating ET adapter. The free length of the spring is preferably such that when it is uncompressed, the sleeve remains on the wall of the central passage. Secondly, if for any reason the connection to the ET adapter has to be opened, the spring-loaded sleeve ensures that when reconnected, a positive seal will again be obtained. Finally, the use of a spring to ensure positive motion, assists in overcoming any friction arising from the tight fit required between the parts to ensure gas-tightness. Such friction may otherwise cause sticking of the sleeve to the wall of the central passage.

It is appreciated, though, that the use of the spring is not meant to be an essential part of this preferred embodiment, and that the sleeve may also be preferably utilized without a spring, similarly to the insert in the embodiments shown in Figs. 2 to 4. Likewise, according to other preferred embodiments, the insert used in the embodiments of Figs. 2 to 4 may also be used, with suitable structural additions, with a spring, with its incumbent advantages.

The internal diameter of the internal bore of the passage is preferably the same as the internal diameter of the inner bore of the ET adapter, such that there is an approximately smooth-walled transition from the ET-adapter to the passage, thereby endowing this embodiment with the advantages mentioned in this respect in the embodiments shown in Figs. 2 to 4. The change in diameter at the sleeve location has a minimal effect, both because of the small change in diameter, and because of the small length of sleeve exposed.

Tests performed on neonatal airway adapters constructed according to all of the preferred embodiments of this invention, as shown in Figs. 2 to 5, indicate that the adapters fulfill the operational requirements for their successful intended use.

Firstly, the adapters connect, without any significant compatibility problems, to all of the most commonly used airway components known to the inventors, including commonly used ET adapters, and the well-known Ballard Closed Suction System, and Bird Flow Adapters.

The void volume is very small, being less than 0.4 cc, and the lengths of the various embodiments of the neonatal airway adapters is also minimal, being 30 mm for the T-version and 36 mm for the Y-version. Because of their small size and aerodynamic internal construction, the pressure drop is minimal, being only an extra 12% when connected to a standard 3.5mm ET set, and even that low value being obtained at the high airway flow rate of 8 l/min.

The response time of the airway system is hardly affected by the inclusion of the neonatal airway adapter. At a flow rate of 8 l/min, the neonatal airway adapter adds an additional 1 to 3 msec to the response time. At 0.6 l/min, an additional 10 to 13 msec is added. By way of comparison, the commonly used, prior art, RSP adapter adds an additional 43 msec. at 0.6 l/min. Even if the neonatal airway adapter according to the present invention is not correctly inserted, and the sliding insert is not flush with the inner wall of the ET adapter, the response time is still acceptable. For a 3 mm gap from the inner wall, the added response time has been measured as being only 23 to 36 msec. at a flow rate of 0.6 l/min., which is still less than that of the RSP adapter.

In a test known as the Micro-drop test with Nebulizer, for determining the prevention of liquid entrance into the sampling line, the Y-version allowed entry of 5ml. of water per hour, and the T-version, only 1 ml. of water per hour. By means of comparison, the RSP adapter allowed entry of 6 ml. of water per hour.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described



hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of various features described hereinabove as well as variations and modifications thereto which would occur to a person of skill in the art upon reading the above description and which are not in the prior art.

## CLAIMS

We claim:

1. An airway adapter comprising:
  - a first end section for connecting to an endotracheal tube adapter having an inner bore, said first end section having a passage formed therein;
  - a second end section for connecting to a ventilating tube connector, said second end section being in fluid communication with said first end section;
  - a sampling port intermediate said end sections in fluid communication with said first end section; and
  - a tubular insert with an internal bore, which slides axially in said passage.
2. An airway adapter according to claim 1 and wherein the internal diameter of said internal bore of said insert gradually increases towards an end of said insert near said sampling port, such that said internal diameter of said internal bore becomes essentially equal to the internal diameter of said passage.
3. An airway adapter according to claim 1 and wherein said insert has a projection adapted to abut against a portion of said first said end section, which provides an axial motion limit into said passage.
4. An airway adapter according to claim 3 and wherein said projection comprises a lip on the external wall of said insert.
5. An airway adapter according to claim 1 and wherein an outer wall of said insert has a surface profile such that the friction between said insert and said passage prevents said insert from sliding freely within said passage.

6. An airway adapter according to claim 1 and wherein said internal bore of said insert at an end of said insert distant from said sampling port, has an internal diameter essentially equal to the internal diameter of said inner bore of said endotracheal tube adapter, thereby providing a virtually smooth-walled passage from said inner bore of said endotracheal tube adapter to said internal bore of said insert.

7. An airway adapter according to claim 6 and wherein said end of said insert distant from said sampling port abuts against said end of said inner bore of said endotracheal tube passage, thereby resulting in virtual elimination of void volume between said inner bore of said endotracheal tube adapter and said internal bore of said insert.

8. An airway adapter according to claim 6 and wherein said virtually smooth-walled passage is operative to allow a breath waveform to pass essentially without affecting its waveform.

9. An airway adapter according to claim 7 and wherein said virtual elimination of void volume is operative to allow a breath waveform to pass essentially without affecting its waveform.

10. An airway adapter according to claim 7 and wherein said virtual elimination of void volume between said inner bore of said endotracheal tube adapter and said internal bore of said insert is effective independently of the relative position in which said endotracheal tube adapter and said airway adapter are mated.

11. An airway adapter according to claim 1 and wherein said sampling port has openings located radially distant from the walls of said passage.

12. An airway adapter comprising:

a first end section for connecting to an endotracheal tube adapter having an inner bore, said first end section having a passage formed therein, said passage having an inner bore and an outer wall;

a second end section for connecting to a ventilating tube connector, said second end section being in fluid communication with said first end section;

a sampling port intermediate said end sections in fluid communication with said first end section; and

a tubular sleeve with an internal bore, which slides axially on said outer wall of said passage.

13. An airway adapter according to claim 12 and also comprising a spring operative to push said sleeve axially in a direction away from said sampling port.

14. An airway adapter according to either of claims 12 and 13, and wherein an internal diameter of said passage increases towards an end of said passage near said sampling port.

15. An airway adapter according to either of claims 12 and 13, and wherein said inner bore of said passage has an internal diameter essentially equal to the internal diameter of said inner bore of said endotracheal tube adapter, thereby providing an approximately smooth-walled transition from said inner bore of said endotracheal tube adapter to said inner bore of said passage.

16. An airway adapter according to either of claims 12 and 13, and wherein said end of said sleeve distant from said sampling port abuts against said end of said inner bore of said endotracheal tube passage, thereby resulting in virtual elimination of void volume between said inner bore of said endotracheal tube adapter and said internal bore of said sleeve.

17. An airway adapter according to claim 15 and wherein said virtually smooth-walled passage is operative to allow a breath waveform to pass essentially without affecting its waveform.

18. An airway adapter according to claim 16 and wherein said virtual elimination of void volume is operative to allow a breath waveform to pass essentially without affecting its waveform.

19. An airway adapter according to claim 16 and wherein said virtual elimination of void volume between said inner bore of said endotracheal tube adapter and said internal bore of said sleeve is effective independently of the relative position in which said endotracheal tube adapter and said airway adapter are mated.

20. An airway adapter according to either of claims 12 and 13, and wherein said sampling port has openings located radially distant from the walls of said passage.

21. An airway adapter according to any of the previous claims and wherein an end of said sleeve distant from said sampling port is constructed of a pliant material.

22. An airway adapter according to any of the previous claims and operative to nullify the effects of differing internal diameters and internal lengths which are used in endotracheal tube adapters.

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
14 December 2000 (14.12.2000)

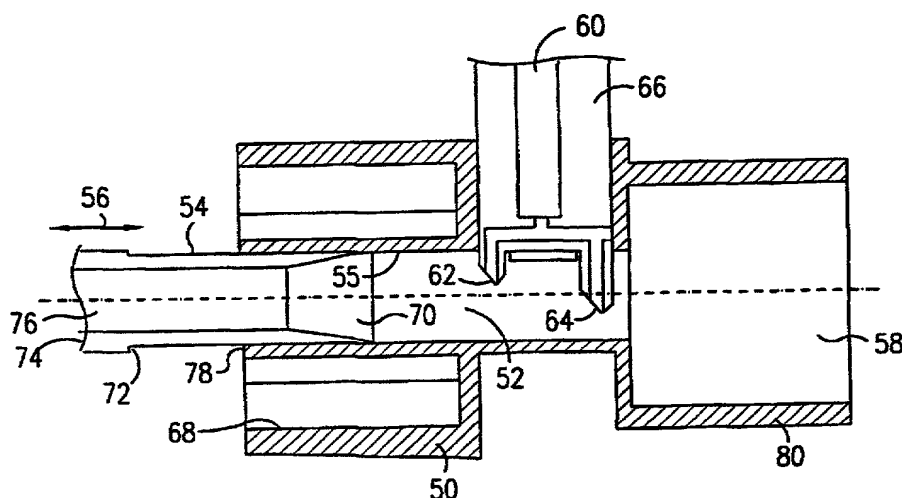
PCT

(10) International Publication Number  
**WO 00/74756 A1**

- (51) International Patent Classification<sup>7</sup>: **A61M 16/00**
- (21) International Application Number: **PCT/IL00/00336**
- (22) International Filing Date: **7 June 2000 (07.06.2000)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:  
**130369** **8 June 1999 (08.06.1999)** **IL**
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- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (81) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).**
- Published:**
- With international search report.
  - Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

[Continued on next page]

(54) Title: **NEONATAL AIRWAY ADAPTOR**



(57) Abstract: This invention is a neonatal airway adaptor (10) with a sliding internal passage (54), which virtually eliminates void volumes (112) within the bore (76) of the airways, such that mixing of the exhaled gases with void gases is reduced, and the waveform of the breath is maintained without undue distortion. Furthermore, the virtual elimination of void volumes reduces the level of re-breathing. The neonatal airway adaptor connects to endotracheal tube adapters in such a way as to nullify the effect of the differing internal diameters (20) and internal lengths which are used in ET adapters currently available. The cross section of the internal bore of the airway through which the breath flows from the ET adapter to the connector of the ventilator is maintained almost constant, especially in the region of the gas sampling point (66), to ensure that reasonable conditions of laminar flow, and accurate sampling are maintained.

WO 00/74756 A1

FIG. 1  
(PRIOR ART)

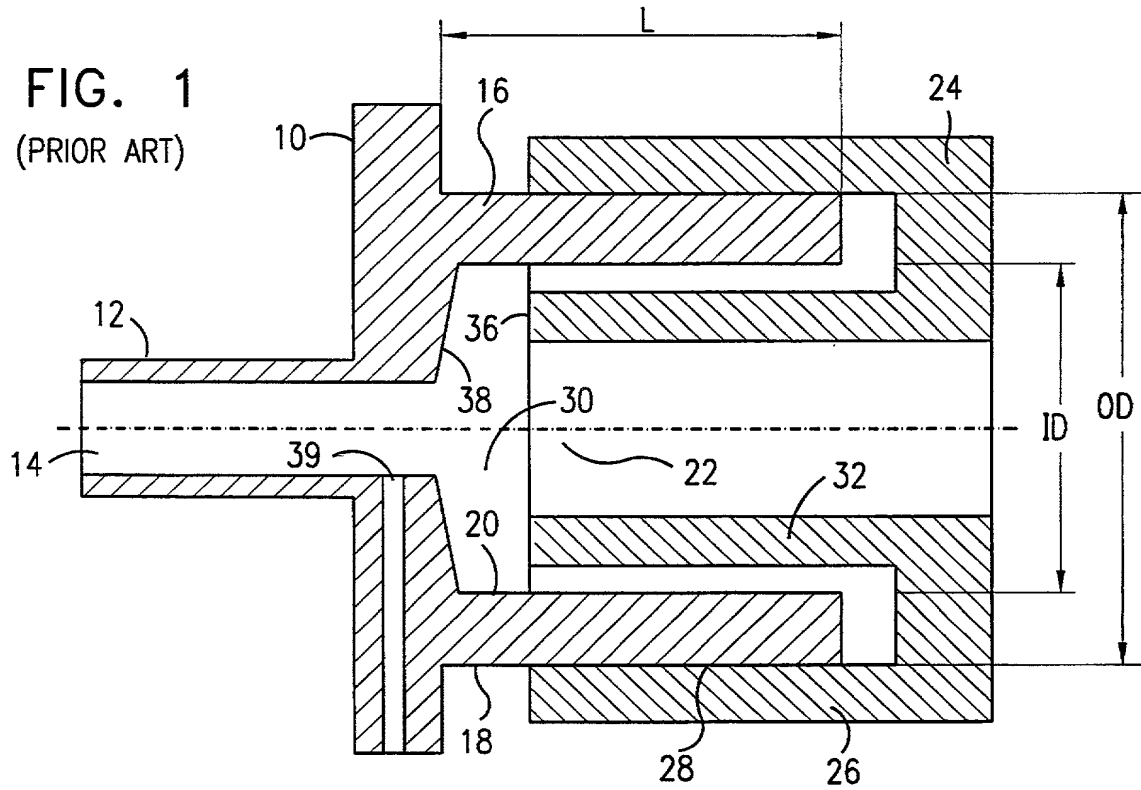


FIG. 2

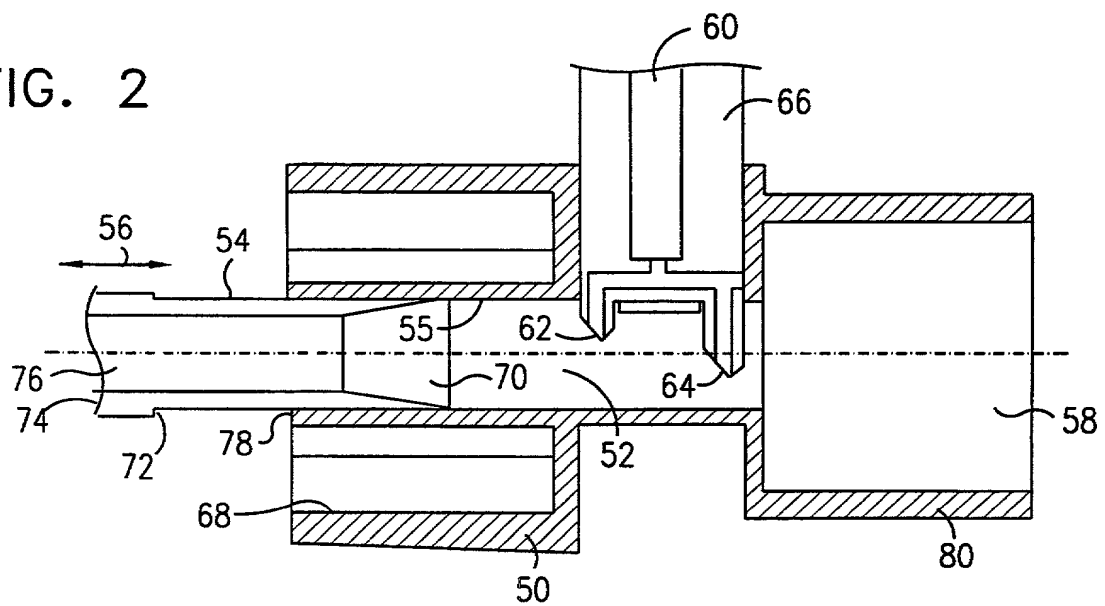


FIG. 3

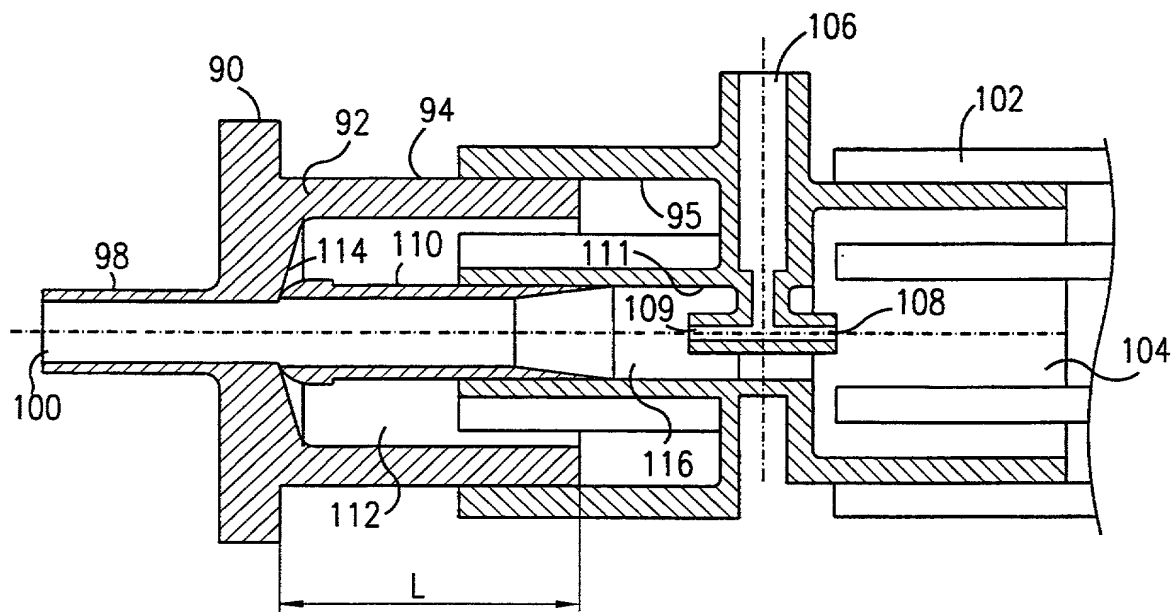


FIG. 4

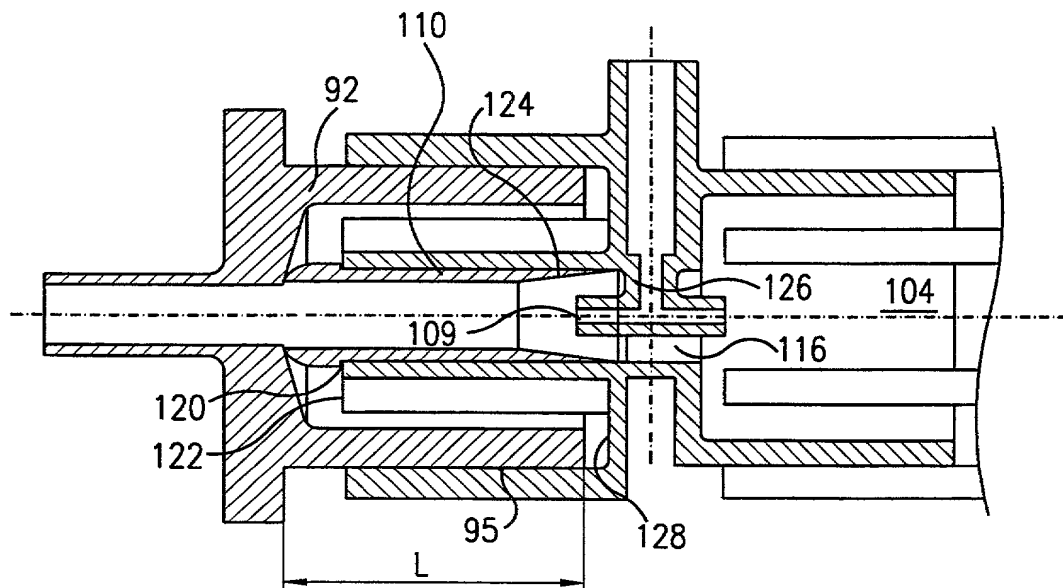
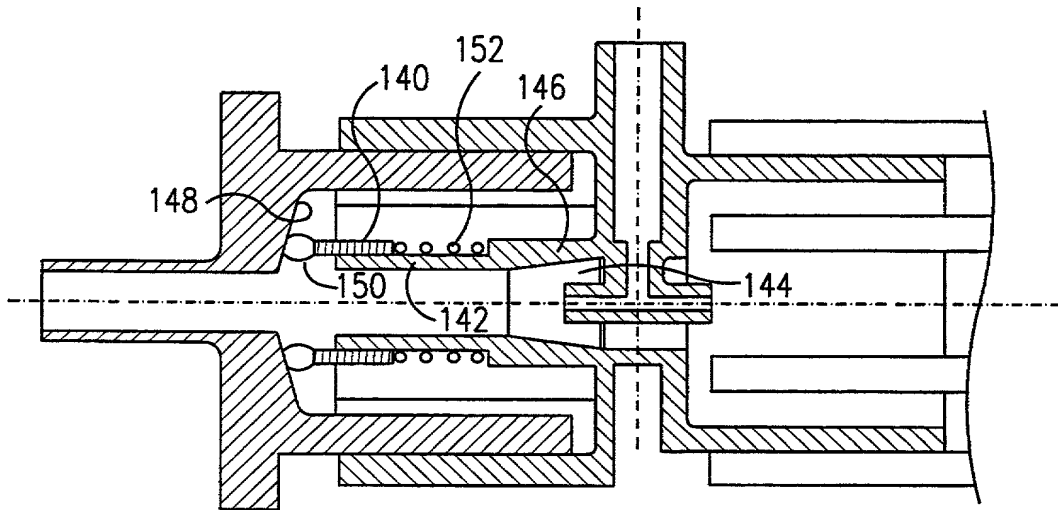


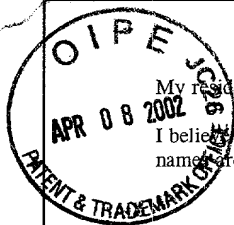


FIG. 5



## COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

(Includes Reference to PCT International Applications)

ATTORNEY DOCKET NUMBER  
6727/OK095

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for and which a patent is sought on the invention entitled:

## NEONATAL AIRWAY ADAPTOR

the specification of which (check only one item below):

☐ is attached hereto.☒ was filed as United States applicationSerial No. 10/009,847on December 7, 2001

and was amended

on \_\_\_\_\_ (if applicable).

☐ was filed as PCT international application

Number \_\_\_\_\_

on \_\_\_\_\_

and was amended under PCT Article 19

on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

## PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 U.S.C. 119
ISRAEL	130369	08 June, 1999	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

Combined Declaration for Patent Application and Power of Attorney (Continued) (Includes Reference to PCT International Applications)				ATTY'S DOCKET NUMBER 6727/OK095	
I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:					
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U.S. APPLICATIONS			STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED	
PCT APPLICATIONS DESIGNATING THE U.S.					
PCT APPLICATION NO	PCT FILING DATE	U.S. SERIAL NUMBER ASSIGNED (if any)			
PCT/IL00/00336	07 June 2000				
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agents to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. Morris Relson #15,108, Gordon D. Coplein #19,165, William F. Dudine, Jr. #20,569, Michael J. Sweedler #19,937, S. Peter Ludwig #25,351, Paul Fields #20,298, Joseph B. Lerch #26,936, Melvin C. Garner #26,272, Ethan Horwitz #27,646, Beverly B. Goodwin #28,447, Adda C. Gogoris #29,714, Martin E. Goldstein #20,869, Bert J. Lewen #19,407, Henry Sternberg #22,408, Peter C. Schechter #31,662, Robert Schaffer #31,194, Robert C. Sullivan, Jr. #30,499, and Joseph R. Robinson #33,448					
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SIGNATURE OF INVENTOR 201		SIGNATURE OF INVENTOR 202		SIGNATURE OF INVENTOR 203	
DATE		DATE		DATE	
Mar. 13, 2002		Mar. 13, 2002			